

REMARKS

Claims 1-22 are pending in the application. With Applicant's submission on October 16, 2008, claim 23 was provisionally withdrawn. No claim has been presently amended. Accordingly, Applicant submits that no new matter has been added.

I. The Priority Date for the Instant Application is July 3, 2003.

The filewrapper for this U.S. application records that Applicant entered the PCT National Phase before the U.S. PTO on January 3, 2006. This PCT Application, published as WO 2005/002495 (on January 13, 2005), has an official International filing date of July 1, 2004 and a claim to a German priority application dated July 3, 2003. All of these dates are acknowledged and accepted by the U.S. PTO in a communication to Applicant "Notice of DO/EO Acceptance", which was mailed on April 20, 2006.

A certified copy of the (foreign) German Priority Document was submitted to the U.S. PTO at the time this application entered the U.S. National Phase on January 3, 2006.

An official English translation of the (foreign) German Priority Document was filed with the U.S. PTO with Applicant's response on October 16, 2008, making these documents of record in accordance with 37 CFR 1.55.

Accordingly, because all of the requirements under 35 USC §119 have been fulfilled, Applicant may properly rely upon the filing date of the submitted German Priority Document, July 3, 2003, in order to overcome any requirements and/or rejections asserted by the U.S. PTO to the instant application.

II. Request for Reconsideration of Election/Restriction Requirement Based on a Non-citable Disclosure

In an Office Action dated December 29, 2008, the Examiner alleges that Applicant was not fully responsive to the prior Office Action (dated October 2, 2008) since "applicant failed to correctly elect a particular inhibitor directed against PCMA4 isoform", citing 37 CFR §1.111. Furthermore, the Examiner states that Applicant "failed to address the recitation of claim 21 which recites addition of other components." Finally, the Examiner requires Applicant to "elect a

particular inhibitor of PCMA4 isoform and identify correctly such group” to fulfill the “required” species election.

Applicant respectfully disagrees with the Examiner’s assessment of the prior art being used in support of the present election/restriction requirement, which, in fact, **is a disclosure that was published after the German priority date for the instant application.**

In the Office Action dated October 2, 2008, the Examiner required Applicant to make an election between Group I (claims 14-22) and Group II (claim 14 insofar as it relates to a method for diagnosing infertility in a human male and claim 23).

As the *basis* for the election/restriction requirement, the Examiner cited the following reference: Schuh *et al.* (Journal of Biological Chemistry, Vol. 279, No. 27, pages 28220-28226, herein “Schuh”; see Office Action, page 3), which has a **publication date of July 2, 2004**. Specifically, the Examiner stated that “the common technical feature in both of the Groups” (i.e. Group I and Group II) “is the PMCA4 inhibitor” which “cannot be said to be a special technical feature...because the PMCA4 inhibitor” is alleged to be disclosed by Schuh. Because the citation of Schuh was improper because it was published **after** the claimed German priority date, an election/restriction requirement grounded in this disclosure cannot properly be made.

Included in Applicant’s response of record, filed on October 16, 2008, a **provisional election** of Group I (and **provisional withdrawal** of claim 23) was made pursuant to 37 CFR 1.143. This action was taken based on an erroneous belief that the election/restriction requirement was, in fact, valid. Because Applicant is entitled to the claimed priority date of July 3, 2003, which is before the publication date of Schuh (July 2, 2004), Applicant respectfully requests that the Examiner reconsider and withdraw the present election/restriction requirement.

Further and favorable consideration of all of the claims of record on the merits is kindly requested.

III. Species Election, Claim 15

In the Office Action dated December 29, 2008, the Examiner requested that Applicant “correctly elect a particular inhibitor directed against PCMA4 isoform.” Consulting the Office Action dated October 2, 2008, the Examiner explicitly stated: “The species are as follows:... applicant may elect a particular **PMCA4 isoform** listed in claim 15” (on page 4).

Applicant respectfully points out that claim 15 recites: “The method according to claim 14, wherein the **PMCA4 inhibitor** is selected from the group consisting of a 5- or 6-carboxyeyoindiacetate...” (emphasis added). Since the claim is directed to a listing of PMCA4 inhibitors and *not* PMCA4 isoforms, Applicant is unable to elect a species, provisionally or otherwise, as required by the Examiner. Accordingly, Applicant seeks clarification from the Examiner as to whether the species election is to a **PMCA4 isoform** or a **PCMA4 inhibitor**, so that a response can be made.

However, per the discussion in Section II, *supra*, Applicant expresses a good faith belief that the election/restriction requirement as a whole, insofar as it is based on the post-published Schuh disclosure, is improper and thus no species election is presently required.

IV. Species Election, Claim 21

In the Office Action dated December 29, 2008, the Examiner indicates that Applicant “failed to address the recitation of claim 21 which recites addition of other components.” Consulting the Office Action dated October 2, 2008, the Examiner explicitly stated: “The species are as follows:...the recitation of claim 21 indicates that the contraceptive composition may further entail additional **components**” and requires Applicant to elect “the presence or absence of additional **components**” (on page 4).

Applicant respectfully points out that claim 21 recites: “The method according to claim 20, further comprising a **conventional contraceptive**” (emphasis added). Claim 20 recites the inhibitor of claim 14 *and* a pharmaceutically acceptable carrier. Since claim 21 recites an additional feature of a “conventional contraceptive” to a composition having a “pharmaceutically acceptable carrier” (which could reasonably be construed as a “component” in a general sense), Applicant is unclear whether the Examiner means “presence or absence” of additional ‘conventional contraceptives’ or

any component generally. Accordingly, Applicant seeks clarification from the Examiner such that a response can be made.

However, per the discussion in Section II, *supra*, Applicant expresses a good faith belief that the election/restriction requirement as a whole, insofar as it is based on the post-published Schuh disclosure, is improper and thus no species election is presently required.

CONCLUSION

Applicants submit that all of the pending issues have been addressed. In addition, Applicants note that nothing in this reply should be construed as an intent to concede any issue with regard to any claim, unless specifically so stated.

No other fees are believed to be due in connection with this correspondence.

The Examiner is welcomed to telephone the undersigned at the number listed below in order to expedite the prosecution of this application.

Respectfully submitted,

Dated: 28 January 2009

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